REMARKS

Claims 1-90 are currently pending in the application.

Applicants provisionally elect Group II, claims 32-62 and 77-90 for prosecution purposes, with traverse. Applicants hereby conditionally withdraw claims 1-31 and 63-76 from prosecution, without prejudice, and request reconsideration of the restriction requirement.

Applicants traverse the restriction requirement based on the following grounds. It is respectfully submitted that the restriction requirement practice was established to promote efficiency of prosecution in the Patent Office. Both groups of claims are classified in class 436 and as such facilitate the purposes for which the restriction requirement practice was established. Since there is a great amount of cross-classification amongst the sub-classes in this class, it is respectfully submitted that examination of all of the claims in a single application would be efficient, thereby promoting the grounds for the establishment of the restriction requirement practice. More specifically, the kit is for use in a method as defined in the claims. Accordingly, they do relate to a single invention. The kit, according to claim 32, is defined such that there are provided means for incubating the TSH receptor with a sample of body fluid and means for reacting the incubated sample of body fluid with at least one binding agent. This is in conformity with the method claims. Accordingly, prosecution of all the claims in a single application would be beneficial. Hence, it is respectfully submitted that restriction should not be required and that Applicants have traversed the restriction requirement. However, as stated above, Applicants have elected the claims of Group II and provisionally withdraw claims 1-31 and 63-76, without prejudice, pending reconsideration of the restriction requirement.

The application is now in condition for allowance, which allowance is respectfully solicited.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

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Dated: October 2, 2001

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231 on October 2, 2001.

Connie Herty

VERSION WITH MARKINGS TO SHOW CHANGES MADE

CLAIMS:

49. (Amended) A kit according to claim 32, wherein [step (d) comprises] said detecting [of] means are capable of detecting labeled or unlabeled TSH bounds to TSH receptor and unbound labeled or unlabelled TSH.

51. (Amended) A kit according to claim 32, wherein [step (d) comprises] said detecting [of] means are capable of detecting labeled or unlabeled TSH receptor and unbound labeled or unlabeled TSH agonist.

57. (Amended) A kit according to claim 32, wherein [step (d) comprises] said detecting [of] means are capable of detecting labeled or unlabeled TSH antagonist bound to TSH receptor and unbound labeled or unlabeled TSH antagonist.

63. (New) A method of screening a sample of body fluid for autoantibodies to (i) a TSH receptor, or (ii) at least a TSH receptor fragment, which method comprises:

(a) providing a source of (i) a TSH receptor or (ii) at least a TSH receptor fragment, said (i) TSH receptor or (ii) TSH receptor fragment each having at least first and second distinct epitope regions, wherein autoantibodies to said (i) TSH receptor or (ii) TSH receptor fragment bind to said first epitope region but not said second epitope region;

(b) providing at least one antibody, or fragment thereof, capable of binding to said second epitope region of said (i) TSH receptor or (ii) TSH receptor fragment;

(c) contacting said (i) TSH receptor or (ii) TSH receptor fragment as provided by step (a) with at least said sample of body fluid being screened and said antibody as provided by step (b), so as to allow:

autoantibodies to said (i) TSH receptor or (ii) TSH receptor fragment, when present in said sample of body fluid being screened, to bind to said first epitope region of said (i) TSH receptor or (ii) TSH receptor fragment; and

said antibody as provided by step (b) to bind to said second epitope region of said (i) TSH receptor or (ii) TSH receptor fragment; and

(d) monitoring binding in step (c) of said autoantibodies and said (i) TSH receptor or (ii) TSH receptor fragment, so as to provide an indication of the presence of autoantibodies to said (i) TSH receptor or (ii) TSH receptor fragment, in said sample of body fluid being screened.

64. (New) A method according to claim 63, wherein said antibody of step (b) comprises a monoclonal antibody, or a recombinant antibody, or fragment thereof, capable of binding to said second epitope region of said (i) TSH receptor or (ii) TSH receptor fragment.

65. (New) A method according to claim 63, wherein said antibody of step (b) comprises a monoclonal antibody or fragment thereof obtainable by the Examples.

66. (New) A method according to claim 63, wherein said antibody of step (b) is immobilized to a solid phase.

67. (New) A method according to claim 63, wherein said antibody of step (b) is labeled.

68. (New) A method according to claim 63, wherein said antibody of step (b) is contacted with said (i) TSH receptor or (ii) TSH receptor fragment prior to contact of said (i) TSH receptor or (ii) TSH receptor fragment with said sample of body fluid being screened in step (c).

69. (New) A method according to claim 63, wherein said antibody of step (b) is contacted with said (i) TSH receptor or (ii) TSH receptor fragment concurrent with or after contact of said (i) TSH receptor or (ii) TSH receptor fragment with said sample of body fluid being screened in step (c).

70. (New) A method according to claim 63, wherein step (c) further comprises contacting a competitor capable of binding with said first epitope region of said (i) TSH receptor or (ii) TSH receptor fragment with said (i) TSH receptor or (ii) TSH receptor fragment, said sample of body fluid being screened and said antibody as provided by step (b).

71. (New) A method according to claim 70, wherein said competitor is selected from the group consisting of TSH, a monoclonal antibody and a recombinant antibody.

72. (New) A method according to claim 70, wherein said competitor is labeled.

73. (New) A method according to claim 70, wherein said competitor is immobilized to a solid phase.

74. (New) A method according to claim 70, wherein said competitor is contacted in step (c) with said (i) TSH receptor or (ii) TSH receptor fragment after contact of said (i) TSH receptor or (ii) TSH receptor fragment with said antibody of step (b).

75. (New) A method according to claim 70, wherein said competitor is contacted in step (c) with said (i) TSH receptor or (ii) TSH receptor fragment before or concurrent with contact of said (i) TSH receptor or (ii) TSH receptor fragment with said antibody of step (b).

76. (New) A method according to claim 63, which further comprises, during or after step (c), contacting a binding agent specific for said autoantibodies present in said sample of body fluid being screened with said (i) TSH receptor or (ii) TSH receptor fragment, said sample of body fluid being screened and said antibody of step (b).

77. (New) A kit for use in screening a sample of body fluid for autoantibodies to (i) a TSH receptor, or (ii) at least a TSH receptor fragment, which kit comprises:

(a) a source of (i) a TSH receptor or (ii) a TSH receptor fragment, said (i) TSH receptor or (ii) TSH receptor fragment each having at least first and second distinct epitope regions, wherein autoantibodies to said (i) TSH receptor or (ii) TSH receptor fragment bind to said first epitope region but not said second epitope region;

(b) at least one antibody, or fragment thereof, capable of binding to said second epitope region of said (i) TSH receptor or (ii) TSH receptor fragment;

(c) means for contacting said (i) TSH receptor or (ii) TSH receptor fragment of (a) with at least said sample of body fluid being screened and said antibody of (b), whereby said contacting means allow:

autoantibodies when present in said sample of body fluid being screened to bind to said first epitope region of said (i) TSH receptor or (ii) TSH receptor fragment; and

said antibody of (b) to bind to said second epitope region of said (i) TSH receptor or (ii) TSH receptor fragment; and

(d) means for monitoring binding of said autoantibodies and said (i) TSH receptor or (ii) TSH receptor fragment, so as to provide an indication of the presence of autoantibodies to said (i) TSH receptor or (ii) TSH receptor fragment in said sample of body fluid being screened.

78. (New) A kit according to claim 77, wherein said antibody of (b) comprises a monoclonal antibody, or a recombinant antibody, or fragment thereof capable of binding to said second epitope region of said (i) TSH receptor or (ii) TSH receptor fragment.

79. (New) A kit according to claim 77, wherein said antibody of (b) comprises a monoclonal antibody or fragment thereof obtainable by the Examples.

80. (New) A kit according to claim 77, wherein said antibody of (b) is immobilized to a solid phase.

81. (New) A kit according to claim 77, wherein said antibody of (b) is labeled.

82. (New) A kit according to claim 77, wherein said contacting means are such as to enable contact of said antibody of (b) with said (i) TSH receptor or (ii) TSH receptor fragment prior to contact of said (i) TSH receptor or (ii) TSH receptor fragment with said sample of body fluid being screened.

83. (New) A kit according to claim 77, wherein said contacting means are such as to enable contact of said antibody of (b) with said (i) TSH receptor or (ii) TSH receptor fragment concurrent with or after contact of (i) TSH receptor or (ii) TSH receptor fragment with said sample of body fluid being screened.

84. (New) A kit according to claim 77, which further comprises a competitor capable of binding with said first epitope of said (i) TSH receptor or (ii) TSH receptor fragment and whereby said contacting means are such as to enable contact of said competitor with said (i) TSH receptor or (ii) TSH receptor fragment, said sample of body fluid being screened and said antibody of (b).

85. (New) A kit according to claim 84, wherein said competitor is selected from the group consisting of TSH, a monoclonal antibody and a recombinant antibody.

86. (New) A kit according to claim 84, wherein said competitor is labeled.

87. (New) A kit according to claim 84, wherein said competitor is immobilized to a solid phase.

88. (New) A kit according to claim 84, wherein said contacting means are such as to enable contact of said competitor with said (i) TSH receptor or (ii) TSH receptor fragment after contact of said (i) TSH receptor or (ii) TSH receptor fragment with said antibody of (b).

89. (New) A kit according to claim 84, wherein said contacting means are such as to enable contact of said competitor with said (i) TSH receptor or (ii) TSH receptor fragment before or concurrent with contact of said (i) TSH receptor or (ii) TSH receptor fragment with said antibody of (b).

90. (New) A kit according to claim 77, which further comprises a binding agent specific for said autoantibodies present in said sample of body fluid being screened and whereby said contacting means are such as to enable contact of said binding agent with said (i) TSH receptor or (ii) TSH receptor fragment, said sample of body fluid being screened and said antibody of (b).